Remarks/Arguments:

Introduction

Claims 1-30 and 32 are pending. Claim 31 has been cancelled.

Claims 1, 3, 8, 11, 16 and 27 have been amended to describe the stent as being a metallic stent with an open lattice structure. Support for these amendments may be found in paragraphs [0026] and [0029].

No new matter is introduced with these amendments.

Section 102 Rejections

Claims 3, 4, 7 and 32 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U. S. Patent No. 5,669,930 to Igarashi (hereinafter "Igarashi"). Applicants respectfully traverse.

Igarashi is directed to a conduit made from silicone rubber. (Igarashi, column 5, line 8). The conduit has a hollow, tubular configuration with the tubular wall being solid, i.e., no open spaces through the stent wall. The internal and external wall surfaces are coated with a layer of poly-monochloro-para-xylylene. (Igarashi, column 7, lines 1-10). The layer has a thickness from 0.01 μm to 20 μm. (Igarashi, column 7, lines 28-29). The conduit is described as insertable into an airway, esophagus or bile duct. (Igarashi, column 1, lines 7-8).

In contrast to Igarashi, the invention as presently defined by independent claim 3 is directed to an implantable stent-graft device. The device comprises a seamless and self supporting tubular non-textile graft of biocompatible polymeric material having a wall thickness of about 10 microns to about 100 microns defining a luminal surface and an exterior surface; and

a radially expandable stent securably disposed over portion of said exterior surface, said stent being a metallic stent having an open lattice tubular structure.

In contrast to Igarashi, the invention as presently defined by independent claim 32 is directed to an implantable graft device. The graft device consists essentially of a seamless and self supporting tubular non-textile graft of biocompatible polymeric material having a wall thickness of about 10 microns to about 100 microns and having opposed open ends to define a fluid passageway therebetween.

Igarashi fails to disclose an implantable stent-graft device comprising, *inter alia,* a radially expandable metallic stent having an open lattice tubular structure and a polymeric graft as set forth in independent claim 3. More specifically, Igarashi fails to disclose, *inter alia*, a metallic stent having an open lattice tubular structure. Moreover, Igarashi fails to disclose that its layer of poly-monochloro-para-xylylene could be a self-supporting, implantable graft as set forth in independent claim 3. Igarashi merely describes its layer of poly-monochloro-para-xylylene as being a coating on a solid rubber conduit.

Thus, Igarashi fails to disclose the invention of independent claim 3.

Further, Igarashi fails to disclose an implantable graft consisting essentially of a biocompatible polymeric material having a wall thickness of about 10 microns to about 100 microns, as set forth in independent claim 32. While the poly-monochloro-xylylene layer of Igarashi may have a wall thickness of 0.01 μm to 20 μm, this layer is described as only being deposited over the exterior and interior surfaces of a solid silicone rubber conduit. Thus, Igarashi fails to disclose the implantable graft consisting essentially of the polymeric material of claim 32.

Thus, Igarashi fails to disclose the invention of independent claim 32.

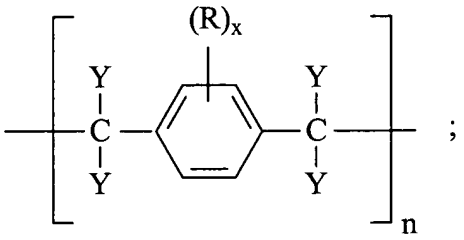
Therefore, reconsideration and withdrawal of the rejection of claims 3, 4, 7 and 32 under 35 U.S.C §102(b) are respectfully requested.

Section 103 Rejections

Claims 1, 2, 5, 6 and 8-30 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 5,669,930 to Igarashi (hereinafter "Igarashi"). Applicants respectfully traverse.

As described above, Igarashi is directed to a solid, tubular silicone rubber conduit having its interior and exterior surfaces coated with a layer of poly-monochloro-para-xylylene having a thickness from 0.01 μm to 20 μm.

In contrast to Igarashi, the invention as presently defined by independent claim 1 is a stent-graft endoprosthesis. The stent-graft endoprosthesis comprises a seamless tubular graft of biocompatible polymeric material having a wall thickness defining a luminal surface and an exterior surface; a radially expandable coated stent securably, circumferentially and axially disposed over said exterior surface, wherein said coated stent is coated with said biocompatible polymeric material, said stent being a metallic stent having an open lattice tubular structure; wherein said biocompatible polymeric material consists essentially of poly-para-xylylene having a formula of



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wherein n is from about 10 to about 10,000, x is from 0 to 4, R, which can be the same or different, is alkyl, aryl, alkenyl, amino, cyano, carboxyl, alkoxy, hydroxylalkyl, carbalkoxy,

hydroxyl, nitro, chlorine, bromine, iodine and fluorine, and Y, which can be the same or different, is hydrogen, chlorine, bromine, iodine and fluorine.

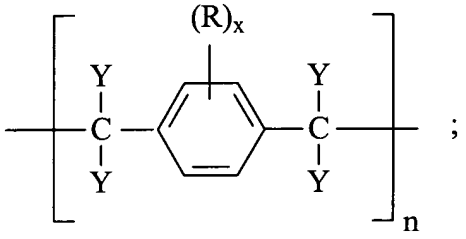
Thus, Igarashi fails to teach or suggest, *inter alia*, a radially expendable metallic stent having an open lattice structure where the stent is coated with the poly-para-xylylene as defined by the chemical formula and, *inter alia*, a tubular graft of poly-para-xylylene disposed over the exterior surface of the stent where the graft is the poly-para-xylylene as defined by the chemical formula.

In establishing a *prima facie* case of obviousness, the cited reference must be considered for the entirety of its teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* Thus, the specific teachings of Igarashi which teach away from the present invention must be considered by the examiner. For example, Igarashi specifically teaches that its coating of poly-monochloro-para-xylylene is to be applied only on the surface of a on a solid rubber conduit.

It is also well established that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction using Applicants' disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993). As Igarashi fails to teach or suggest a metallic stent having an open lattice tubular structure, any attempt to modify their teachings to the same is hindsight reconstruction. Further, Igarashi fails to teach or suggest a stent-graft comprising, *inter alia*, a coating of poly-para-xylylene as defined by the chemical formula on the stent and graft of poly-para-xylylene as defined by the chemical formula.

Thus, Igarashi fails to teach or suggest the stent-graft endoprosthesis as presently defined by independent claim 1.

Similarly, Igarashi fails to teach or suggest the stent-graft endoprosthesis of independent claims 11, which comprises a seamless tubular non-textile graft of biocompatible polymeric material having a wall thickness defining a luminal surface and an exterior surface; and a radially expandable stent securably disposed over a portion of said exterior surface, said stent being a metallic stent having an open lattice tubular structure; wherein said polymeric material consists essentially of a poly-para-xylylene having a formula of



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wherein n is from about 10 to about 10,000, x is from 0 to 4, R, which can be the same or different, is alkyl, aryl, alkenyl, amino, cyano, carboxyl, alkoxy, hydroxylalkyl, carbalkoxy, hydroxyl, nitro, chlorine, bromine, iodine and fluorine, and Y, which can be the same or different, is hydrogen, chlorine, bromine, iodine and fluorine because Igarashi fails to teach or suggest, *inter alia*, a metallic stent having an open lattice tubular structure.

Thus, Igarashi fails to teach or suggest the stent-graft endoprosthesis as presently defined by independent claim 11.

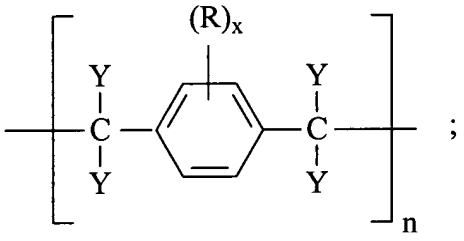
Moreover, Igarashi fails to teach or suggest the stent-graft endoprosthesis, as presently defined in independent claims 8, or the stent-graft device, as presently defined in independent claim 3, because Igarashi fails to teach or suggest, *inter alia*, a metallic stent having an open lattice tubular structure.

Thus, Igarashi fails to teach or suggest the stent-grafts as presently defined by independent claims 3 and 8.

Further, Igarashi fails to teach or suggest the methods of the invention, as presently defined by independent claims 16 and 27, because Igarashi fails to teach or suggest, *inter alia*, methods for producing a stent-graft endoprosthesis, in particular, producing a stent-graft endoprosthesis comprising a metallic stent having an open lattice tubular structure and a poly-para-xylylene polymeric graft.

Thus, Igarashi fails to teach or suggest the methods as presently defined by independent claims 16 and 27.

Finally, as Igarashi requires its thin layer of poly-monochloro-para-xylylene to be directly associated with a silicon rubber conduit to form a unitary insertable device, Igarashi fails to teach or suggest the endoprosthesis as presently defined by independent claim 29, which endoprosthesis consists essentially of a seamless tubular non-textile graft of biocompatible polymeric material having a wall thickness of about 10 microns to about 250 microns defining a luminal surface and an exterior surface; wherein said polymeric material is a poly-para-xylylene having a formula of



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wherein n is from about 10 to about 10,000, x is from 0 to 4, R, which can be the same or different, is alkyl, aryl, alkenyl, amino, cyano, carboxyl, alkoxy, hydroxylalkyl, carbalkoxy, hydroxyl, nitro, chlorine, bromine, iodine and fluorine, and Y, which can be the same or different, is hydrogen, chlorine, bromine, iodine and fluorine.

Thus, Igarashi fails to teach or suggest the endoprosthesis as presently defined by independent claim 27.

Similarly, Igarashi fails to teach or suggest the implantable graft device as presently defined by independent claim 32, because Igarashi fails to teach or suggest an implantable graft device consisting essentially of a seamless and self supporting tubular non-textile graft of biocompatible polymeric material having a wall thickness of about 10 microns to about 100 microns and having opposed open ends to define a fluid passageway therebetween.

Thus, Igarashi fails to teach or suggest the implantable device as presently defined by independent claim 32.

Thus, Igarashi fails to teach or suggest the inventions as presently defined by independent claims 1, 3, 8, 11, 16, 27, 29 and 32. Therefore reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) of independent claims 1, 3, 8, 11, 16, 27, 29 and 32, and all claims dependent therefrom.

Summary

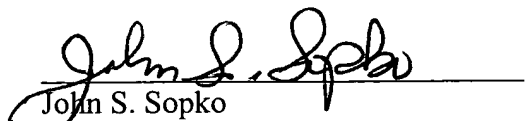
Therefore, Applicants respectfully submit that independent claims 1, 3, 8, 11, 16, 27, 29 and 32, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if

any, under 37 C.F.R § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,



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